IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC., *et al.,* Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC., *et al.,* Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW

DECLARATION OF ALEXANDER M. KLIBANOV, Ph.D.

I, Dr. Alexander M. Klibanov, declare:

1. I am the same Alexander M. Klibanov who has submitted an opening expert report (my "Opening Invalidity Report") and a supplemental expert report in the above-captioned litigation on behalf of Avadel CNS Pharmaceuticals, LLC ("Avadel") on January 17 and 27, 2023, respectively. My professional background, qualifications, and experience are outlined in detail in my Opening Invalidity Report.

2. I am currently a Professor Emeritus of Chemistry and Bioengineering at the

Massachusetts Institute of Technology ("M.I.T."), where I taught and conducted research for over 40 years. During more than 50 years as a practicing chemist, I have extensively researched, published, taught, and lectured in many areas of chemistry, including biological, pharmaceutical formulation, general, and medicinal.

3. I have been working on this case as an expert since May 2021 and have met with Avadel's attorneys ("Counsel"), both in person and remotely, a number of times to discuss, among other things, Jazz's formulation patents.

4. On February 4, 2023, Counsel's Audra Sawyer, Esq., sent me Dr. Steven R. Little's Opening Expert Report ("Dr. Little's Infringement Report") (*see* Ex. J)[1] along with copies of the asserted Jazz's sustained-release patents, including the '488 patent (Ex. B), to review in order to prepare a rebuttal expert report on non-infringement.

5. I reviewed Dr. Little's Infringement Report and, in light of it, carefully re-read the claims and specifications of the sustained-release patents. As a result, I noticed for the first time that, whereas the preamble and certain claim limitations of, for example, the '488 patent require an "active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate," other claim limitations require ***only*** "gamma-hydroxybutyrate" as the active ingredient.

6. Notably, I saw that Dr. Little's Infringement Report (*see, e.g.*, Ex. J, ¶¶ 62, 65, 76) fails to distinguish between gamma-hydroxybutyrate and ***sodium*** gamma-hydroxybutyrate (*i.e.*, sodium oxybate). The two are markedly different: "gamma-hydroxybutyrate" is an anion (*i.e.*, a negatively-charged ion), and "sodium gamma-hydroxybutyrate" is an electrostatically-neutral

[1] All citations to "Ex. __" refer to the exhibits that are attached to Avadel's letter brief, filed contemporaneously herewith.

salt (i.e., an ionic compound formed when the anion gamma-hydroxybutyrate binds to the cation Na^+). Yet, Dr. Little's Infringement Report repeatedly relies on the presence of sodium gamma-hydroxybutyrate in Avadel's accused product to ostensibly meet claim limitations requiring only "gamma-hydroxybutyrate." I explained this to Counsel in a meeting on February 6, 2023.

7. Jazz's formulation patents' use of the terms "gamma-hydroxybutyrate" and "oxybate" is consistent with their aforementioned plain meaning. The patents use these terms to refer to anions, specifically unbound anions, and hence exclude salts, such as "sodium gamma-hydroxybutyrate." The '079 and '782 patent specifications define "gamma-hydroxybutyrate" and "oxybate" as "the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid." *E.g.*, Ex. F, '079 patent at 3:59-61. The sustained-release patents are consistent with this meaning: both their claims and specifications contrast "gamma-hydroxybutyrate" with "pharmaceutically acceptable salts of gamma-hydroxybutyrate." *E.g.*, Ex. B, '488 patent at claim 1 ("A formulation comprising immediate release and sustained-release portions, each portion comprising at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate, …."), 5:34-38, 9:50-52.

I declare under penalty of perjury under the laws of the United States of America that the foregoing declaration is true and correct to the best of my knowledge.

Executed on February 28, 2023,

in Del Mar, California

Alexander M. Klibanov, Ph.D.